Full Text OD-97-005

CENTER FOR CHIROPRACTIC RESEARCH

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PURPOSE

The Office of Alternative Medicine (OAM) was mandated by Congress in 1991 and permanently established within the Office of the Director, National Institutes of Health (NIH), through the National Institutes of Health Revitalization Act of 1993 (Public Law 103-43, Section 209). The mission of the OAM is to encourage and support the investigation of complementary and alternative medical (CAM) practices, with the ultimate goal of integrating validated alternative medical practices into health and medical care.

The demographics, prevalence, and patterns of use of unconventional medicine in the United States have been described (New England J. Med. 328:246-352, 1993). The most relevant findings are the following: a) most people use unconventional therapies for chronic rather than life-threatening medical conditions; b) users of alternative therapies do not inform their primary care physicians; c) extrapolation to the United States population suggests that Americans made

approximately 425 million visits to providers of unconventional therapy during 1990; and d) expenditures associated with alternative therapies appear similar to non-reimbursed expenses incurred for all hospitalizations in the United States. These findings indicate that alternative medicine modalities occupy a larger role in the self-health care of U.S. citizens than previously understood.

Chiropractic is one of the most used forms of CAM by the U.S. Public. The goal of this RFA initiative is to encourage research of chiropractic by establishing a Center for Chiropractic Research. Such a Center will make available to investigators interested in chiropractic the resources necessary for the conduct of high quality research.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," an initiative for setting national health policy and priorities. Although Healthy People 2000 does not currently specify a CAM or Chiropractic objective, this RFA involves priority areas within the Healthy People 2000 objectives, which involve alternative medical health care. Applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic Colleges of Chiropractic or other chiropractic training institutions, either alone or in collaboration with other chiropractic institutions or with a conventional biomedical institution, including domestic for-profit and not-for- profit organizations, public and private organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, Federally recognized Indian Tribal organizations, and eligible agencies of the Federal government. As the focus of this RFA is chiropractic medicine, substantive involvement of a College of Chiropractic or other chiropractic training institution is highly encouraged. Applications may include foreign components, but foreign organizations are not eligible to apply. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U24), an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Under the cooperative agreement, the NIH purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Details of the responsibilities, relationships and governance of the study to be funded under cooperative agreement(s) are discussed later in this document under the section "Terms and Conditions of Award."

FUNDS AVAILABLE

Approximately $500,000 in total costs (direct plus indirect) will be committed in the first year to fund one award from a qualified applicant. This award may be up to five funded years.

This funding level is dependent on the receipt of applications of high technical and scientific merit, and the continued availability of funds. Because the nature and scope of applications may vary, it is anticipated that the award size could vary.

RESEARCH OBJECTIVES

Background

The Office of Alternative Medicine (OAM) is mandated by Congress to identify and evaluate unconventional health care practices used by members of the U.S. public. Of these practices, chiropractic care is one of the mostly widely used by the public. Chiropractors are licensed in all fifty states, and chiropractic treatments for musculoskeletal disorders are often reimbursed by health insurance plans. It has been estimated that 5-10% of the U.S. population use chiropractic services at a cost of approximately $2 billion dollars, annually. One third to one half of these visits are for low-back pain. In recent years, there has been increased research on chiropractic care, some of which suggests the efficacy of spinal manipulation for certain type of low back pain. Although not systematically studied, major complications from chiropractic care appear to be rare. Nevertheless, there is a relative paucity of research on the efficacy and effectiveness of such chiropractic care for musculoskeletal disorders, including chronic pain, and little preclinical work on the biological mechanisms underlying chiropractic manipulation of the vertebral column.

Purpose of the RFA

A variety of health care providers employ the modalities of manipulation and mobilization for the treatment of musculoskeletal disorders; however, the expressed purpose of this RFA is to provide a mechanism to examine the potential effectiveness and validity of chiropractic therapies, and to provide clinical/scientific/technical assistance to chiropractic investigators as they develop their research projects. The establishment and support of a Center for Chiropractic Research, under the auspices of the OAM, will meet these objectives. The Center will support a multi-disciplinary group of researchers and clinicians to perform basic, preclinical, clinical, epidemiologic and or health services research of chiropractic. The Center will provide many of the resources necessary of the conduct of high quality research, including an environment for training future scientists. Finally, the Center will encourage collaboration between basic and clinical scientists, and between the chiropractic and conventional medical communities.

In general, insufficient scientific data are currently available that address safety and efficacy questions for chiropractic care of musculoskeletal disorders, including chronic pain. Many chiropractic practitioners are not affiliated with research institutions currently able to provide the research infrastructure necessary to facilitate the study of chiropractic manipulations. Research conducted at the Center for Chiropractic Research will provide useful pilot data to determine the appropriateness of conducting larger studies on chiropractic approaches for the treatment of back maladies and related musculoskeletal disorders. It is expected that work begun at the Center will provide the basis for subsequent investigator-initiated research grant applications to the NIH.

Center Concept

The Center for Chiropractic Research is viewed as a first step in expanding the national infrastructure for research of chiropractic. It will support planning for new interdisciplinary programs involving experienced investigators from chiropractic and conventional medicine. It will provide clinical/scientific/technical assistance to investigators both on and off site.

Key personnel must have expertise in areas such as biostatistics, computer processing, data management, protocol design, survey design, questionnaire development, basic laboratory evaluations, patient record data analysis, patient registries, development of databases, clinical and behavioral epidemiology, health education, health promotion and clinical trial methodology. The following personnel positions may be supported by the Center grant: Principal Investigator/Center Director (0.5 FTE), Administrative Manger/Assistant/Secretary (0.5 FTE), Computer Specialist/ Analyst/Biostatistician/Epidemiologist (0.5 FTE). Salaries of personnel should be charged to the grant in proportion to the time dedicated to Center activities. All

positions must be adequately justified in the application, including a detailed description of the proposed duties and relevance to specific Center objectives.

Specific objectives for the Center include:
o Establishing linkage of academic centers with Chiropracticinvestigators;
o Establishing a network of Chiropractic clinicians and investigators in specific topic areas;
o Prioritizing performing research related to the chiropractic treatment of musculoskeletal disorders;
o Linking investigators with common clinical interventions to each other and to technical expertise necessary to pursue research goals;
o Establishing an advisory committee to provide program direction and advice to the principal investigator of the Center, including prioritization of research protocols;
o Evaluate the feasibility of using data from chiropractic practitioners for research projects;
o Developing a mechanism for scientific/technical merit review of proposed studies from investigators;
o Developing a bibliographic resource on chiropractic topics to be made accessible to the public;
o Develop workshops, seminars, etc. for training purposes; and
o Acting as an institutional focus for training in research methodology, bioethics, biostatistics, clinical trial design, epidemiological studies, health services studies and basic laboratory methods.

Chiropractic institutions that do not have the full capability within their own institution to respond to this RFA are encouraged to involve other institutions, both chiropractic and conventional, through consortium agreements.

Research Focus

Applications must include two research projects proposed for Center use. These projects may be up to three years in length. Projects already underway at the time of the application are applicable if not currently supported by the NIH. In addition, for each project, a justification for use of the Center is required, including an estimate of resources to be used.

The Center will provide limited support for these research projects. A total of $200,000 (total cost) will be available in Year One for the research projects outlined in the application. Additional projects may be added in subsequent years up to $350,000 (total costs) per year for all projects. General purpose equipment, such as computers, and personnel will not be supported with these

funds. It is expected that the project investigators will obtain additional funding to support their research and salaries through federal or other sources.

Research topics include, but are not limited to, randomized, controlled clinical trials of chiropractic care for the treatment of musculoskeletal disorders, studies examining the rates and types of treatment complications, the amount and type of treatment necessary to achieve significant outcomes, cost-effectiveness analysis of chiropractic care and projects examining the underlying, biomedical/pathophysiological basis of chiropractic therapies.

CENTER ACTIVITIES

On a continuing basis, the Center will be expected to prioritize the top research areas concerning chiropractic medical treatments for musculoskeletal disorders including acute and chronic pain. This could be accomplished by holding research agenda conferences, conducting systematic reviews of the science in proposed areas of research, or by performing meta-analyses where appropriate. As part of the prioritization process, the Center is to establish and maintain a comprehensive bibliographic database on Chiropractic. The OAM will assist the Center in this endeavor. Eventually, the public will have access to this database through the Internet

Within the first year, the Center should establish the infrastructure necessary to perform the research outlined in the application and begin this research. The Center will be expected to disseminate research findings in a timely manner through peer-reviewed publications. It is expected that new projects will begin by year three of the award up to a maximum of $350,000 (total costs) per year for all projects. Center investigators are encouraged to seek additional sources of research support.

The Center must propose a mechanism for prioritizing research projects and a mechanism for scientific/ technical merit review of the projects. This can be in the form of a scientific advisory board or can employ independent reviewers, in a manner similar to that used at NIH. Center resources may only be used for projects prioritized and approved by the Center's Advisory Committee.

Advisory Committee

Center oversight is charged to an Advisory Committee (AC) to be appointed by the Principal Investigator on a rotating basis. The AC shall not be chaired by the Principal Investigator who will serve in an ex officio capacity only. The AC should meet at least quarterly and minutes of the

meeting kept. These minutes shall be made available to NIH staff upon request. The AC should be a cross- section of eight to twelve individuals familiar with the Center's research activities. It is encouraged that the AC includes both faculty and non-faculty. However, all AC members should have training in either chiropractic medicine, conventional medicine or biomedical research. The AC shall include a biostatistician and epidemiologist to assist with the review of projects and the optimal approaches for subsequent data analysis.

Besides prioritizing research projects submitted by Center or, if applicable, Consortium investigators, the AC should periodically review Center operations to ensure that Center resources are used for the most scientifically worthy projects. The AC should take an active role in encouraging younger faculty member to perform research and assist them in applying appropriate research concepts and methods. Support for the AC should be explicitly budgeted and justified.

Clinical/scientific/technical Assistance Activities

Each application must demonstrate the ability to provide clinical/scientific/technical assistance to potential chiropractic investigators and propose a plan for providing assistance to chiropractic investigators in the chosen program areas. These activities may include, but are not limited to, the following examples of assistance:

o Choice of research methods appropriate to the chiropractic intervention;
o Development of appropriate chiropractic protocols;
o Study design;
o Methods of data collection, management, and data analysis;
o Quality control procedures;
o Development of appropriate methods to assure safety of human subjects involved in research protocols;
o Safety issues;
o Case review methods;
o Provide guidelines for applicants to use for clinical evaluation and data collection, e.g., NCI best case series;
o Develop procedures for reporting adverse effects;
o Preparation for Institutional Review Board approvals and FDA Investigational New Drug applications; and
o Preparation for workshops, seminars, etc. for chiropractic investigators on relevant research topics.

One purpose of this research program is to assist Chiropractic investigators in determining whether they have adequate preliminary data to propose specific defined pilot studies or make other applications for peer-reviewed research support.

Training

The Center is to serve as an environment for training health professionals in research on topics related to chiropractic. In addition, the Center should implement a program designed to introduce chiropractic students, residents and fellows to biomedical research in an effort to attract these individuals into research careers. Formal courses or seminars may be set up for this goal. The courses should be relevant to diverse areas of research and could include an array of topics, such as biostatistics, design of clinical trials, computer skills and bioethics. Student participation in ongoing research projects is also encouraged. Support for training should be explicitly budgeted and justified.

The Center is expected to seek supplemental support for its training program through such mechanisms as the NIH National Research Service Award Institutional Research Training Grant (T32) or Individual Postdoctoral Fellowships (F32).

SPECIAL REQUIREMENTS

Applicants should propose an appropriate structure for the center application to meet the research goals and objectives stated above.

The Principal Investigator (PI) must make a substantial commitment (e.g., 30%) to the Center.

The PI or Director of the Center will be a member of a coordinating committee consisting of all PIs or Directors of OAM-supported Research Centers. The purpose of the Committee is to share experiences, discuss common problems and solutions, help in the development of networks of investigators, establish common guidelines and procedures for pilot studies and, where feasible, other activities. The Center for Chiropractic Research must agree to use any common guidelines and procedures agreed upon by the Coordinating Committee (e.g., process for systematic review of literature, bibliographic database management, structure of research opportunity disposition summaries, report formats, etc.).

The PI or Director is expected to attend and participate in at least two, two-day Coordinating Committee planning/progress meetings per year in Bethesda or Rockville, Maryland. A scientific

presentation of Center-supported research is required once a year at these meetings. Funds should be included in the budget to cover these trips.

Any publications involving this OAM project must follow NIH publication policies, including citation of the NIH grant.

The following terms and conditions will be incorporated into the award statement and provided to the Principal Investigator(s) as well as the institutional official at the time of award.

TERMS AND CONDITIONS OF AWARD

The administrative and funding instrument used for the Centers is a cooperative agreement (U24), an "assistance" mechanism in which substantial NIH scientific and programmatic involvement with the awardee is anticipated during the performance of the agreement.

Under the cooperative agreement, the OAM purpose is to assist and stimulate the Center's planning and implementation by involvement in and working with the Center in a partner role. The OAM role is not to assume primary direction, responsibility, or a dominant operating role in the Center. Consistent with this concept, the primary role and total responsibility for Center programs resides with each Center. The Center and the OAM as noted below will share specific tasks and activities in completing the agreement.

These special Terms of Award are in addition to and not in lieu of applicable U.S. Office of Management and Budget administrative guidelines, HHS Grant Administration Regulations at 45 CFR Parts 74 and 92, and other HHS, PHS, and NIH Grant Administration policy statements.

1. Awardee Rights and Responsibilities

The Awardee will have primary and lead responsibilities for the project as a whole, but are expected to collaborate and cooperate with the Coordinating Committee, as well as with OAM and National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) staff. The Awardee is expected to prioritize, facilitate and support research, provide clinical/scientific/ technical assistance to potential Center (Consortium) investigators and initiate a training program as outlined in the application.

The Awardee will establish an Advisory Committee to provide scientific and administrative oversight. The Advisory Committee will be composed of a cross-section of individuals

knowledgeable in chiropractic medicine, conventional medicine or biomedical research, including a biostatistician and epidemiologist. These individuals are not limited to Center, or, if applicable, Consortium, faculty. The AC is expected to meet at least quarterly, with minutes of the meeting kept. The minutes will be made available to NIH staff upon request.

The Advisory Committee is charged with both prioritizing projects submitted to the Center (or Consortium) and periodically reviewing Center (Consortium) activities to ensure that Center objectives, as outlined in the application, are being met.

The Awardee is expected to initiate and maintain a comprehensive bibliographic database on chiropractic, with public access being the eventual goal.. Approximately every six months, the Center and OAM will electronically exchange collected citations

The Awardee will retain custody of, and have primary rights to, the data developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

2. NIH Staff Responsibilities

The OAM Project Scientist will have substantial scientific and programmatic involvement in assisting the Awardee in the project, participating in technical assistance activities, referring members of the public to the Center for information or assistance, assisting in the development of bibliographic resources in Chiropractic, coordinating and involving NIH resources of clinically relevant activities outside of Chiropractic. NIAMS will designate a Program Officer and a Grants Management Specialist to provide administrative oversight of the grant, and will serve as scientific, technical, and programmatic advisors to the OAM during administration of this award.

OAM Staff will assist the Center with the establishment and maintenance of the bibliographic database on Chiropractic. Approximately every six months, the OAM and Center will electronically exchange collected citations. Eventually, the public will have access to this database through the Internet.

3. Collaborative Responsibilities

A Center Coordinating Committee, composed of the PIs of each OAM-supported Research Center and the OAM Director, or designated representative, has the primary responsibility for developing and implementing common procedures, guidelines, and criteria across centers,

establishing common procedures and guidelines for pilot studies and other activities where feasible. The Center for Chiropractic Research agrees to use any common guidelines and procedures agreed upon by the Coordinating Committee (e.g., process for systematic review of literature, bibliographic database management, structure of research opportunity disposition summaries, report formats, etc.). The OAM Director, or designated representative, is a voting member of the Center Coordinating Committee and will serve as Chair.

The Coordinating Committee will establish subcommittees as appropriate; OAM staff will provide assistance and support to the sub-committees as appropriate.

The OAM Project Scientist will coordinate NIH Alternative Medicine activities with Center activities.

4. Arbitration

Any disagreement that may arise on scientific and programmatic matters within the scope of the cooperative agreement and between award recipients and the OAM may be brought to arbitration. An arbitration panel will be composed of three members: one selected by the Center Principal Investigator; a second member selected by the OAM; and, the third member selected by the two prior selected members. This special arbitration procedure in no way effects the awardee's right to appeal an adverse action that is appealable in accordance with PHS regulations at 42 CFR Part 50, Subpart D, and HHS regulation at 45 CFR Part 16.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided, that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 18, 1994 (FR 59 14508-14513), and in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

LETTER OF INTENT

Applicants are asked to submit, by April 1, 1997, a letter of intent that includes the number and title of this RFA; the name, address, and telephone number of the Principal Investigator (s); the identities of other key personnel and participating organizations or institutions, if any; and a title describing the proposed research. Although a letter of intent is not required, is not binding, and does not enter into the review of applications, the information that it contains will be especially helpful to the OAM in planning for the review of applications, estimating the potential work-load, and avoiding conflicts of interest in the review process.

The letter of intent is to be sent to:

Richard L. Nahin, Ph.D.
Office of Alternative Medicine
National Institutes of Health
Building 31, Room 5B-38
Bethesda, MD 20892-2182
FAX: (301) 480-3519

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for this cooperative agreement. These forms are available at most institutional offices of sponsored research, from the OAM program administrator named above or from the World Wide Web at http://grants.nih.gov/grants/funding/funding.htm. Prior to writing the application, applicants should carefully read the instructions provided with form PHS 398 and this RFA.

The total page limitation of the application, as specified in the instructions of the Form PHS 398, do not apply to this RFA. Applicants may spend up to 25 pages to describe Center activities and, in addition, up to 25 pages for each of the two research projects, excluding bibliographies. The two research projects should follow the PHS 398 format.. Each of the six points listed under Human Subjects in the PHS 398 application must be addressed for those studies involving human subjects. Although not required at the time of the application, Institutional Review Board and Institutional Animal Care and Use Committee must be obtained for each project listed, if appropriate, within 60 days of submission.

The RFA label available in the PHS 398 application package must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the

application. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a typewritten, signed original of the application, four signed photocopies, and the completed checklist in one package to:

DIVISION OF RESEARCH GRANTS
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, mail one additional complete copy of the application to the following RFA program administrator:

Richard L. Nahin, Ph.D.
Office of Alternative Medicine
National Institutes of Health
Building 31, Room 5B-38
Bethesda, MD 20892-2182

Applications must be received by May 9, 1997. If an application is received after the date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one previously reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such an application must follow the guidance in the PHS Form 398 application instructions for preparation of revised applications, including an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

General Considerations

Upon receipt, applications will be reviewed for completeness by the DRG and responsiveness by the OAM. Incomplete applications will be returned to the applicant without further consideration.

If the application is not responsive to the RFA, OAM staff will return the application to the applicant.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the DRG in accordance with the NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Advisory Council for NIAMS.

Review Criteria

An initial review group convened by the NIH DRG will assess the technical and scientific merit of the applications submitted based on three general areas: 1) the technical merit of the research proposals; 2) the institutional commitment and environment; and 3) the potential of the proposed center to enhance the level of chiropractic research. Below are specific criteria that will be evaluated by the reviewers. The final priority score will reflect the peer reviewers' overall assessment based on their judgements of these criteria:

o Relevance to chiropractic and chiropractic research

o Degree of substantive involvement of chiropractic training institutions

o Scientific and technical merit of the proposed approaches for conducting the research projects

o Adequate statistical, methodological and other appropriate scientific expertise, as dictated by the proposed research projects

o Qualifications and clinical/research training and experience of the Principal Investigator and staff

o Demonstration that the appropriate chiropractic community linkages exist

o Availability of resources necessary to perform research assistance activities

o Proposed organization and activities of the Advisory Committee, including description of process to prioritize research proposals; although it is not necessary to name members at this time, the process by which members will be chosen should be specified;.

o Plans for the initiation and maintenance of a comprehensive bibliographic database on chiropractic;

o Appropriateness of the proposed budget;.

o Appropriateness of the proposed training plan;.

o Evidence of the applicant institution's commitment to research and to the proposed Center; this can include, but is not limited to, office and laboratory space, clinical support, administrative support, faculty release from academic duties, support for Center training agenda, etc

o Demonstrated willingness to work as part of the OAM Centers Coordinating Committee and with OAM and NIAMS staff; and

o If a consortium is planned, the applicant must demonstrate the effectiveness of the relationships among the member institutions. The applicant should address both current relationships, as well as the functions and contributions of each consortium member in regards to proposed Center activities. In addition, the component institutions of the consortium must demonstrate adequate commitment to the Center.

AWARD CRITERIA

Applications recommended by the NIH Initial Review Group and by the appropriate national advisory council will be considered for award based on: a) scientific and technical merit as determined by peer review, b) program relevance and balance, c) availability of funds, d) responsiveness to the goals and objectives of the RFA.

Award of funds for the approved future years of the grant will require submission of a noncompeting continuation application, PHS form 2590, to NIAMS at least two months prior to the anniversary date of the award. In addition, an annual progress reports must be submitted to the OAM in accordance with guidelines established by the Coordinating Committee. Failure to supply either the PHS form 2590 or the annual report in a timely manner will impede release of outyear funding.

Schedule

Letter of Intent Receipt Date: April 9, 1997
Application Receipt Date: May 9, 1997
Review by Advisory Council: September 4-5, 1997
Anticipated Award Date: September 30, 1997

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues should be directed to:

Richard L. Nahin, Ph.D.
Office of Alternative Medicine
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B-38
Bethesda, MD 20892-2182
Telephone: (301) 496-4792
FAX: (301) 480-3519
Email: NahinR@OD31EM1.OD.NIH.GOV

Direct inquiries regarding fiscal matters to:

Vicki L. Maurer
Grants Management Specialist
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building Room 5AS.49A - MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3504
FAX: (301) 480-5450
Email: maurerv@ep.niams.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.213. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99- 158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Parts 52 and 45 CFR Part 74 [and Part 92 when applicable for State and Local governments]. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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